PRIVILEGED AND CONFIDENTIAL
ATTORNEY WORK PRODUCT

PROPOSALS TO SUBJECT CIGARETTES TO FDA OR CPSC JURISDICTION

Tobacco products are generally exempt from regulation by the Food and Drug Administration (FDA) and Consumer Product Safety Commission (CPSC). Anti-tobacco advocates apparently have chosen FDA regulation of cigarettes as one of their major policy objectives, and they are currently engaged in two efforts to subject cigarettes to FDA jurisdiction. First, petitions have been filed with the FDA urging it to assert jurisdiction over low tar/low nicotine cigarettes and the proposed RJR smokeless device. Second, Congressman Bob Whittaker has proposed legislation -- H.R. 3294 -- to create a new FDA regulatory regime for cigarettes.

A. Summary of Effects of Proposals for FDA Control

FDA's statute creates specific and distinct regulatory schemes for classes of products: foods, drugs, cosmetics, medical devices, veterinary medicines, and so on. The scheme to be applied to a product follows from the category to which that product is assigned.[1] If cigarettes are to be brought within

[1] In other words, FDA cannot create a new scheme for a new type of product, but may only apply an established
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traditional FDA regulation, they must be determined to be either "drugs" or "foods," and regulated as such. Under either classification, FDA could be compelled to take various actions which could well be tantamount to immediate and total prohibition of cigarettes:

1. If viewed as "drugs," cigarettes would probably be ruled to be "new drugs" for which FDA approval of a application is required by law. To obtain such approval, the application would need to contain extensive animal toxicology, as well as human clinical data, sufficient to demonstrate that the products are safe and effective for their intended use. Until such approval was obtained, the cigarettes would be illegal and marketing could be prohibited by FDA.

2. If viewed as "foods" or "drugs," cigarettes could only contain ingredients that are both safe and suitable for their use. FDA would have authority to rule on whether sufficient data exists to establish that the various additive ingredients used in the products are safe and appropriate. Again, until FDA has approved the various ingredients, their use could be prohibited and any cigarette product containing them would be subject to legal action.

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scheme that Congress designed as generally appropriate for a class of products.

3. If viewed as "drugs," cigarettes would have to be labeled with adequate directions for use and adequate warnings against unsafe use, as determined by FDA. If FDA concludes that such labeling cannot be written for understanding by law persons, it may classify cigarettes as a "prescription drug," thereby prohibiting sale except on a physician's specific order for an individual patent.

In addition to these problems, subjecting cigarettes to the regulatory framework designed by Congress for drugs or foods would impose other significant burdens:

1. Whether cigarettes are classified as "foods" or drugs," manufacturing plants for such products would be subject to FDA's "Good Manufacturing Practices" regulations and inspection at any time by FDA inspectors. If cigarettes are viewed as "drugs," these manufacturing sites would also be required to register as drug establishments

2. If classed as "drugs," companies would be subject to extensive reporting regulations under which adverse reactions from using such cigarettes would be required to be publicly filed with on a timely basis.

3. If cigarettes were viewed as "drugs," all changes in product formula or manufacturing procedures might also be subject to preclearance by FDA.

B. The Whittaker Bill

H.R. 3294 creates a new regulatory structure for tobacco products. Under this legislation, FDA would have the power to: (1) limit or ban any additive that is "unsafe and presents unnecessary increased risks to health" (and tobacco itself could be found to be an additive); (2) prohibit "any added poisonous or deleterious substance which may render [a tobacco product] injurious to health; (3) establish limits on the levels of tar, nicotine, carbon monoxide, and "other harmful constituents," and require disclosure of the amounts of those constituents on packages "or by other means"; (4) mandate disclosure of additives, require a package warning regarding addiction and take action against false and misleading labeling (and possibly advertising); and (5) tightly regulate tobacco manufacturing processes to prevent contamination of tobacco products. The Whittaker bill would also establish a national minimum age of 18 for purchase of cigarettes, ban sampling and coupons, and allow the federal government to regulate the "form, manner and sale of tobacco products."

C. History of Exclusion of Cigarettes from FDA and CPSC Jurisdiction

Congress has correctly recognized that the balance to be struck between the alleged health risks of

smoking and the unquantifiable pleasure that people derive from smoking is a political issue that should not be delegated to the technical expertise of any federal agency. As a result, Congress has struck this balance itself by permitting the continued sale of cigarettes while insisting on increasingly detailed warnings. The fact that virtually every American is well aware of the alleged risk of smoking -- both from the mandated warnings on the packages and advertising, as well as the public debate over smoking and health -- demonstrates that there is no reason to second-guess that decision and call for some special regulation by FDA or CPSC.

Moreover, the laws that those agencies enforce were written by Congress for entirely different types of products. Cigarettes do not fit within the schemes established for foods, drugs, or durable consumer products. It makes no more sense to subject cigarettes to FDA's jurisdiction by calling them "foods" or "drugs" than to call cigarettes "securities" and so vest responsibility in the SEC.

1. FDA

FDA has recognized that the regulation of cigarettes is not within its legal authority. In December 1977, FDA rejected a petition by Action on Smoking and Health ("ASH"), calling for the general regulation of cigarettes by FDA as drugs. This action

was subsequently upheld by Action On Smoking Health v. Harris, 655 F.2d 236 (D.C. Cir. 1980).

FDA ruled that Congress intended products to be regulated as "drugs" only when those who manufactured or sold them made specific claims of therapeutic benefit or an intent to affect the structure or function of the human body. Cigarettes, for which no such claims have been made, did not meet this statutory standard for regulation as a drug.

FDA similarly rejected a subsequent petition by ASH calling for the regulation of filter cigarettes as "medical devices". Again, FDA looked to see whether these products met the broad legal standard that Congress adopted to define FDA's jurisdiction. In that case, FDA held that the filter was not a device unless the manufacturer made some specific therapeutic claims for it. The claim that a filter simply reduced tar and nicotine in the cigarette smoke was not considered by FDA to be a therapeutic claim for purposes of the FDA act. (The issue of filter cigarettes is once again before the FDA in connection with a new petition by the Coalition on Smoking and Health.)

This is not to say that FDA has been reluctant to regulate a particular cigarette where a manufacturer has attempted to sell his product based on some specific health claim. For example, in the 1950s, FDA acted

against cigarettes which made claims that they would "prevent respiratory diseases, common colds," or would curb the appetite and lead to weight reduction. The critical point is that FDA recognizes its statute establishes regulatory standards and requirements designed for classes of products, and that the scheme applicable to one class may make no sense when applied to another class of product. Thus, drugs must be shown efficacious for their intended therapeutic purpose, while foods do not because they have no such therapeutic purpose. Cigarettes as traditionally marketed simply do not fit within any of the regulatory schemes designed by Congress and assigned to FDA.

FDA has clearly been correct in assessing the limits of its jurisdiction, and Congress should not now try to force cigarette regulation into a system of FDA regulation that is not the appropriate vehicle for balancing the alleged risks and clear pleasures of smoking. First, it is clear that cigarettes are not a "food" where FDA regulation is primarily concerned with the issue of adulteration -- unintended contaminants in a product. Although the cigarette industry has been criticized on many points, no one has suggested that there is any such adulteration problem in our manufacturing practices. In contrast to the horror stories that have circulated for many years -- and are

still common -- in such industries as meatpacking, there is no evidence that there is any need for government action in maintaining the cleanliness in cigarette manufacturing plants. (In this connection we might invite the Congressmen to come to Richmond to visit our facility.) In short, if the issue is one of protecting the American consumer from "adulterated" products, the government should spend its time and money in other industries where the problems of potential adulteration are much greater and where the products are used by consumers (including children) without any warning that they may contain such a health hazard.

Similarly, it is clear that it would be inappropriate to regulate cigarettes as "drugs". FDA's system of regulation has been created to consider the safety and efficacy of "drugs" which are intended for therapeutic purposes. As noted above, that distinction has been followed by FDA in regulating only those cigarettes which make claims that they actually treat or prevent some disease. But that issue is very different from the naked attempt to regulate cigarettes which make no such therapeutic claims. Such regulation would be totally inappropriate because FDA has no ability to make a "risk/benefit" determination in the case of cigarettes. Unlike "drugs" which are intended for a specific therapeutic purpose -- where the risks of

unintended side effects can be balanced against the efficacy of the drug in providing its therapeutic effects, cigarettes are simply recreational products which give people pleasure.

In this regard, it is crucial to note that the fact that cigarettes contain nicotine and nicotine has some pharmacological action obviously does not classify the product as a "drug" as that term is used in FDA regulation. Many products contain chemical compounds which have such a pharmacological action. For example, coffee contains caffeine which, in sufficient doses, can be a powerful stimulant. And FDA does regulate pure caffeine when it is sold as a "drug" -- that is, when a company manufacturers a caffeine product such as "No-Doz" and sells the product to keep consumers awake. But no one at FDA or Congress has ever suggested that FDA regulate coffee as a drug.

D. CPSC

For many of the same reasons, the regulation of cigarettes should not be entrusted to the CPSC. Congress made this decision when it enacted the CPSC Act but expressly excluded tobacco. Despite the suggestions of our critics that this was simply a naked political compromise, the fact is that CPSC was never intended to have any special expertise that would lend itself to the regulation of cigarettes.

The principal role of the CPSC is to require corrections, or to warn about, hidden defects in the design or function of some product. The CPSC is not intended to be an organization which bans products which have some risk. Most notably, CPSC has not acted to ban items used for simple pleasure and recreation except where the manufacturer could take some action to correct a design defect or to warn unaware consumers about the risks of a product.

Thus, for example, CPSC may well require the manufacturers of football helmets to correct some hidden defect in the design which the manufacturer can change without impinging on the practical use of the helmet. In other cases, CPSC may require the manufacturer to provide a warning of some unknown danger in the improper use of the helmet. But CPSC has never attempted -- and has no special competence -- to try to ban footballs themselves even though everyone knows that there are certain demonstrable risks in the game and that each year children are permanently injured as a result. Like Congress, CPSC has correctly recognized that it has no ability to make the basic judgment that a particular activity, or product, should be banned outright simply because there are risks which cannot be properly weighed against the unquantifiable pleasure of a particular activity.

E. Ingredients

As a fallback position, our opponents may attempt to secure FDA regulation over the non-tobacco ingredients added to cigarettes. Such legislation, unless it contained "grandfather" provisions exempting existing ingredients, could obviously prove troublesome. Our response should be that, as described in greater detail in the memorandum concerning ingredients, the ingredients added to tobacco are, for the most part, "GENERALLY RECOGNIZED AS SAFE" (GRAS)(although this is in a food rather than inhalation situation); that there is no scientific evidence that the minute amounts of ingredients in cigarettes add, in any way, to the alleged risks of smoking; and that, perhaps most importantly, Congress decided only three years ago that this matter should be handled by having HHS review the list of all ingredients and then making recommendations. The companies provided HHS with that information, but to date HHS has not indicated that there are any problems with the ingredients list.